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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,486	12/19/2000	Alan S. Waggoner	92053CONCIPCON	6161

7590 08/16/2002

NIXON & VANDERHYE P.C.,
110 NORTH GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1627

DATE MAILED: 08/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/740,486

Applicant(s)
Waggoner

Examiner
Padmashri Ponnaluri

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 12, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above, claim(s) 9-12, 15, 19, and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 14, 16-18, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

Art Unit: 1627

DETAILED ACTION

1. This application is a continuation of application 08/745,712, which is a continuation-in-part of application 07/831,759, which is a continuation of 06/854,347.
2. Claims 1-8 have been canceled and new claims 9-16 have been added by the amendment A, filed on 12/12/01; new claims 17-24 have been added by the amendment B filed on 12/19/01.
3. Claims 9-24 are currently pending in this application.
4. Applicant's election with traverse of group III, claims 17-19, in Paper No. 10, filed on 3/4/02 is acknowledged. The traversal is on the ground(s) that group II claims are drawn to cyanine dye falls within the luminescent dye of group III inventions. This is found persuasive and group II inventions are grouped together with group III inventions and examined together in this application.
5. Applicants election of species without traverse cyanine dye as component and nucleotide as component, filed on 3/4/02; and 'hydroxysuccinimide' as reactive group in claim 16, and 'CH₃-H-CH₃' for X and Y, filed on 6/12/02 has been considered.
6. Claims ~~4~~ 1-12, and 21-24 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 10.
7. Claims 15 and 19 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected species invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 10.

Art Unit: 1627

8. Claims 13-14, 16-18 and 20 are currently being examined in this application.
9. The new abstract filed on 4/12/01 has been fully considered and entered into the application.
10. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 17-18 and 20 is rejected under 35 U.S.C. 102(b) as being anticipated by either US Patent 4,404,289 (MASUDA et al) or US Patent 4,405,711 (MASUDA et al).

Masuda et al (the '289 patent) disclose methods for immunochemical measurement of trace component. The reference discloses that eh antigen or antibody (refers to protein) labeled with spectral sensitizers such as cyanine dyes of formula C (i.e., see column 10). The reference discloses that the disclosed spectral sensitizers are particularly advantageous as the labeling substances since these dyes are excellent in binding to the trace components such as antigen or antibody. The reference discloses the formula of the cyanine dye of formula C in columns 11-13.

Art Unit: 1627

The reference clearly anticipates the claimed invention.

Masuda et al (the '711 patent) discloses a method of assay for a trace component such as antigen, antibody or enzyme utilizing immunochemical reaction or enzyme reaction in combination with photographic detection system comprising optical density. The reference discloses that the spectral sensitizer employed for labeling a trace component such as antigen or antibody or synthetic substrate, include cyanine dyes (i.e., see column 10). The reference clearly anticipates the claimed invention.

14. Claims 17-18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Waggoner et al (Biophysical Journal, vol. 33, 1981, page 292a).

Waggoner et al disclose that the reactive sulfhydryl group on the F1 region of cattle rhodopsin has been covalently labeled with a cyanine dye. The absorption of the dye at 660 nm is sensitive to conformational changes of rhodopsin that occur following a short and intense light flash. Thus the reference clearly anticipates the claimed invention.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U. S. P. Q. 645 (Fed. Cir. 1985); *In re Van Ornum*,

Art Unit: 1627

686 F.2d 937, 214 U. S. P. Q. 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 U. S. P. Q. 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 U. S. P. Q. 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

16. Claims 13-14, 16-18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,225,050. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims 1-3, 9-11 are drawn to a method of imparting luminescence to a component and claims 4-8 are drawn to a luminescence labeled component. The luminescence label of the reference is same as the instant claim luminescent label (cyanine dye). Thus it would have been obvious to use the same cyanine dye used in the reference method and in the component to label different component of the instant claims..

17. Claims 13-14, 16-18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,627,027. Although the conflicting claims are not identical, they are not patentably distinct

Art Unit: 1627

from each other because the reference claims are drawn to a method of imparting luminescence to a component by adding cyanine dye of given structure to the component. The cyanine dye used in the reference method is same as the cyanine dye attached to the component of the instant claims. The reference in claim 10 recites that the product or component to be labeled with the cyanine dye is either proteins, cells, nucleic acids or DNA. Thus, it would have been obvious to use the cyanine dyes and the method of imparting luminescence to a component taught by the reference to get the luminescent labeled component of the instant claims.

18. Claims 13-14, 16-18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,569,766. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims are drawn to a water soluble luminescent dye which dye is same as the cyanine dye used to label the components of the instant claims. It would have been obvious to use the luminescent dye of the reference to label a component (i.e., protein or nucleotide) to obtain a luminescent labeled component.

19. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is


Art Unit: 1627

on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mckane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1627
14 August 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER